



# **Proposed Revised Accreditation Standards**

**June 1, 2009**

## Standards – The Three Domains

The AAHRPP Accreditation Standards allocate the criteria for accreditation of Human Research Protection Programs into the following three Domains:

<b>Organization</b>	<b>IRB or Ethics Committee</b>	<b>Researcher and Research Staff</b>
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The "Organization" is the entity that assumes responsibility for the Human Research Protection Program and applies for accreditation. The entity may be an academic institution, clinic, hospital, managed care organization, contract research organization, or a corporate entity, such as a pharmaceutical or biotechnology company, or an independent review board. Despite great dissimilarities in how such entities are structured, the Organization Domain identifies those elements that must be evident, albeit in various different forms, in an entity that seeks accreditation for its Human Research Protection Program.

The Domain of IRB or Ethics Committee refers to the arrangements that the Organization has made for an *independent* review of ethical aspects of each research protocol involving human participants. Such activities are generally carried out by an institutional review board (IRB) or Ethics Committee (EC). Organizations with multiple IRBs or ECs might have a general oversight office or an individual with oversight responsibility. In these complex structures the functions and activities are split between the oversight office or individual with such responsibility and the IRBs or ECs. The review and other activities of the IRB or ECs are concerned with protecting the rights and welfare of the participants. In the review process, IRBs or ECs must ensure that the scientific validity of a research protocol is considered as well as the risks and potential benefits to participants and benefits that might accrue to society. In addition, IRBs are responsible for reviewing research on an ongoing basis, monitoring reports of new information affecting risks and potential benefits, and assuring that the interests of research participants are protected.

The Researcher and Research Staff Domain includes the various arrangements that the Organization has made for assuring that individuals who plan to conduct research — whether as a principal investigator, co-investigator, or other member of a research team — understand and fulfill their responsibilities. Fundamentally, these responsibilities stem from the fact that an individual conducting research enters into arrangements that may intentionally expose human participants to some degree of risk — whether physical, psychological, economic, legal or social — for scientific purposes.

There is no single "right" way for integrating the three Domains into a high-quality Human Research Protection Program. Rather, each entity seeking accreditation will evidence its own unique approach to meeting the various Standards. Altogether, there are 15 AAHRPP Standards within three Domains. Each Domain is introduced by general commentary and a statement of the Standards relevant to that Domain. Each Standard is followed by one or more Elements. AAHRPP provides the Evaluation Instrument for Accreditation to Organizations to evaluate their Human Research Protection Program in relation to the Standards and Elements.

## **Domain I: Organization**

**Commentary:** The Organization Domain describes structural characteristics and key functions of the entity that assumes responsibility for the Human Research Protection Program and that applies for accreditation. The organizational structure is the means by which organizations meet the responsibilities of the Human Research Protection Program. These broad responsibilities are met by establishing a formal process to monitor, evaluate, and continually improve the protection of human research participants; dedicating resources sufficient to do so; exercising oversight of research protection; educating investigators and research staff about their ethical responsibility to protect research participants; and, when appropriate, providing a mechanism to intervene in research and to respond directly to concerns of research participants. The Organization applies its Human Research Protection Program to all research, regardless of funding, conducted domestically or internationally.

**Standard I-1: The Organization has a systematic and comprehensive Human Research Protection Program that affords protections for all research participants regardless of funding source. Individuals within the Organization are knowledgeable about and follow the policies and procedures of the Human Research Protection Program.**

Element I.1.A. The Organization has and follows written policies and procedures for determining when activities are overseen by the Human Research Protection Program. Laws, codes, regulations, and guidance are applied when defining the activities that the Human Research Protection Program oversees.

Element I.1.B. The Organization delegates responsibility for the Human Research Protection Program to an official with sufficient standing, authority, and independence to ensure implementation and maintenance of the program.

Element I.1.C. The Organization has and follows written policies and procedures that allow the IRB or EC to function independently of other organizational entities in its role in protecting research participants.

Element I.1.D. The Organization has and follows written policies and procedures setting forth the ethical standards and practices of the Organization. These policies and procedures are available to Sponsors, Researchers, Research Staff, research participants, and the IRB or EC.

Element I.1.E. The Organization has and follows written policies and procedures for an education program that evaluates, and contributes to the improvement of, the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.

Element I.1.F. The Organization has and follows written policies and procedures for reviewing the scientific or scholarly validity of a proposed research study. Such procedures are coordinated with the ethics review process.

Element I.1.G. The Organization has and follows a process in policies and procedures that identifies applicable laws in the localities where it conducts research and takes them into account in the review and conduct of research.

**Standard I-2: The Organization ensures that the Human Research Protection Program has resources sufficient to protect the rights and welfare of research participants, taking into consideration the research activities that the Organization conducts or oversees.**

**Standard I-3: The Organization's transnational research activities are consistent with the principles set out in its Human Research Protection Program and meet the same levels of protection of research participants as research conducted in the Organization's principal location while complying with local laws and cultural context.**

**Standard I-4: The Organization responds to the concerns of research participants.**

Element I.4.A. The Organization has and follows written policies and procedures that establish a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives that permits them to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research protocol.

Element I.4.B. The Organization conducts activities designed to enhance understanding of human research by participants, prospective participants, or their communities, when appropriate.

Element I.4.C. The Organization or Researchers involve community members in the design and implementation of research and the dissemination of results, when appropriate.

**Standard I-5: The Organization measures and improves, when necessary, compliance with organizational policies and procedures and applicable laws, codes, regulations, and guidance. The Organization also measures and improves, when necessary, the effectiveness and efficiency of the Human Research Protection Program.**

Element I.5.A. The Organization conducts audits or surveys, or uses other methodologies to assess compliance with the policies and procedures and the efficiency and effectiveness of the Human Research Protection Program.

Element I.5.B. Based on objective data, the Organization identifies strengths and weaknesses of the Human Research Protection Program, makes improvements, when necessary, and monitors the effectiveness of the improvements.

Element I.5.C. The Organization has and follows written policies and procedures so that Researchers and Research Staff may bring forward to the Organization concerns or suggestions regarding the Human Research Protection Program, including the ethics review process.

Element I.5.D. The Organization has and follows written policies and procedures for addressing allegations and findings of non-compliance with Human Research Protection Program requirements. The Organization works with the IRB or EC to ensure that participants are protected when non-compliance occurs.

**Standard I-6: The Organization has and follows written policies and procedures to ensure that research is conducted so that financial and other interests are identified and managed, minimized, or eliminated.**

Element I.6.A. The Organization has and follows written policies and procedures to identify and manage, minimize, or eliminate financial interests of the Organization that could influence the conduct of the research or the integrity of the Human Research Protection Program, and to separate competing Organizational interests from ethics review functions.

Element I.6.B. The Organization has and follows written policies and procedures to identify and manage, minimize, or eliminate individual financial interests of Researchers and Research Staff. The Organization works with the IRB or EC in ensuring that financial interests are managed, minimized, or eliminated, when appropriate.

Element I.6.C. The Organization has and follows written policies and procedures to identify and manage, minimize, or eliminate interests - other than financial - of Researchers and Research Staff that could bias research. The Organization works with the IRB or EC in ensuring that the interests are managed, minimized, or eliminated, when appropriate.

**Standard I-7: The Organization has and follows written policies and procedures to ensure that the use of any investigational or unlicensed test article complies with all applicable legal and regulatory requirements.**

Element I.7.A. The Organization secures assurances from the Sponsor that the manufacture and formulation of investigational or unlicensed test articles conform to legal and regulatory requirements.

Element I.7.B. The Organization has and follows written policies and procedures to ensure that the handling of investigational or unlicensed test articles meets organizational standards relating to pharmacy requirements, inventory control, and documentation.

Element I.7.C. The Organization has and follows written policies and procedures for compliance with federal regulations governing emergency use of an investigational or unlicensed test article.

**Standard I-8: The Organization works with public, industry, and private Sponsors to apply the requirements of the Human Research Protection Program to all participants.**

Element I.8.A. The Organization has a written agreement with the Sponsor that addresses medical care for research participants with a research-related injury, when appropriate.

Element I.8.B. In studies where Sponsors conduct research site monitoring visits or conduct monitoring activities remotely, the Organization has a written plan with the Sponsor that the Sponsor promptly reports to the Organization findings that could affect the safety of participants or influence the conduct of the study.

Element I.8.C. The Organization has a written agreement with the Sponsor that addresses provisions for monitoring the data to ensure the safety of participants and for periodically or urgently sending data and safety monitoring reports to the Organization.

Element I.8.D. Before initiating research, the Organization has a written agreement with the Sponsor about plans for disseminating findings from the research and the roles that Researchers and Sponsors will play in the publication or disclosure of results.

Element I.8.E. When participant safety could be directly affected by study results, the Organization addresses in the written agreement with the Sponsor how results will be communicated to study participants.

## **Domain II: IRB or Ethics Committee**

**Commentary:** Within a Human Research Protection Program, responsibilities must be delegated for providing ethical review and oversight of research. These responsibilities can be distributed differently in different Organizations; in many Organizations, the Institutional Review Board (IRB) or Ethics Committee (EC) along with the support personnel and systems provide these functions. In more complex organizations, there might be multiple IRBs or ECs, a general oversight office, or individual organizational officials with oversight responsibilities. This Domain of Standards sets forth requirements for the ethical oversight of research. An IRB or EC is a body established under law, regulations, or code to protect the rights and welfare of human research participants. The Human Research Protection Program must have mechanisms in place to ensure the independence of its ethical review and oversight functions from other units within the organization, particularly with respect to decision-making regarding the ethics of research involving human participants.

### **Standard II-1: The structure and composition of the IRB or EC are appropriate to the amount and nature of the research reviewed.**

Element II.1.A. The IRB or EC has and follows written policies and procedures requiring protocols or research plans to be reviewed by individuals with appropriate scientific or scholarly expertise.

Element II.1.B. The Organization has and follows written policies and procedures to separate competing business interests from ethics review functions.

Element II.1.C. The IRB or EC has and follows written policies and procedures so that members and consultants do not participate in the review of protocols or research plans in which they have a conflict of interest, except to provide information requested by the IRB or EC.

Element II.1.D. The IRB or EC has a qualified chair and vice-chair and qualified members and staff. Membership and composition of the IRB or EC are periodically reviewed.

Element II.1.E. The IRB or EC is comprised of members to permit appropriate representation at the meeting for the types of research under review, and this is reflected on the IRB or EC roster. One or more unaffiliated members are represented on the IRB or EC, and one or more members can represent the general perspective of participants.

Element II.1.F. The IRB or EC meets regularly, members have sufficient time to review materials prior to meeting, and meeting workloads allow for appropriate discussion of each item on the agenda.

### **Standard II-2: The IRB or EC evaluates each research study to ensure the protection of participants.**

Element II.2.A. The IRB or EC has and follows written policies and procedures for determining when activities are exempt from applicable laws and regulations. Such policies and procedures indicate that exemption determinations are not to be made by Researchers or others who might have a conflict of interest regarding the studies. This function may be delegated to an entity other than the IRB or EC.

Element II.2.B. The IRB or EC has and follows written policies and procedures for addressing protection of participants in research that is exempt from applicable regulations. This function may be delegated to an entity other than the IRB or EC.

Element II.2.C. The IRB or EC has and follows written policies and procedures for conducting operations and meetings by the convened IRB or EC.

Element II.2.C.1. – Development and use of the agenda

Element II.2.C.2. – Recording of members present and absent, alternate members, and establishment of a quorum

Element II.2.C.3. – Determination and management of IRB or EC member conflict of interest

Element II.2.C.4. – Use of materials and technology during meetings

Element II.2.C.5. – Voting mechanisms and options

Element II.2.C.6. – Role of the chair and vice chair

Element II.2.D. The IRB or EC has and follows written policies and procedures to conduct reviews by the convened IRB or EC.

Element II.2.D.1. – Initial review

Element II.2.D.2. – Continuing review

Element II.2.D.3. – Review of proposed modifications to research studies

Element II.2.E. The IRB or EC has and follows written policies and procedures to conduct reviews by the expedited procedure.

Element II.2.E.1. – Initial review

Element II.2.E.2. – Continuing review

Element II.2.E.3. – Review of proposed modifications to research studies

Element II.2.F. The IRB or EC has and follows written policies and procedures for addressing unanticipated problems involving risks to research participants or others.

Element II.2.G. The IRB or EC has and follows written policies and procedures for suspending or terminating previously approved research, if warranted, and for reporting these actions as appropriate.

Element II.2.H. The IRB or EC has and follows policies and procedures for managing multi-site research by defining the responsibilities of participating sites that are relevant to the protection of research participants, such as reporting of unanticipated problems or interim results.

**Standard II-3: The IRB or EC approves each research study according to criteria based on applicable laws, codes, regulations, and guidance.**

Element II.3.A. The IRB or EC has and follows written policies and procedures for identifying and analyzing potential sources of risk and measures to minimize risk. The analysis of risk includes a determination that the risks to participants are reasonable in relation to potential benefits to participants and to society.

Element II.3.B. The IRB or EC has and follows written policies and procedures for reviewing the plans for data and safety monitoring in research protocols, when applicable, and determines that the plans provide adequate protection for participants.

Element II.3.C. The IRB or EC has and follows written policies and procedures to evaluate the equitable selection of participants, when applicable.

Element II.3.D. The IRB or EC has and follows written policies and procedures to review proposed participant recruitment methods, advertising materials, and participation payment arrangements and permits them when they are fair, accurate, and appropriate.

Element II.3.E. The IRB or EC has and follows written policies and procedures to evaluate the proposed arrangements for protecting the privacy interests of research participants during and after their involvement in the research.

Element II.3.F. The IRB or EC has and follows written policies and procedures to evaluate proposed arrangements for maintaining the confidentiality of identifiable data, when appropriate, preliminary to the research and during and after the conclusion of the research.

Element II.3.G. The IRB or EC has and follows written policies and procedures to evaluate the consent process.

Element II.3.H. The IRB or EC has and follows written policies and procedures to evaluate the consent document and to require that the Researcher and Research Staff properly document the consent process.

Element II.3.I. The IRB or EC has and follows written policies and procedures for approving waivers or alterations of the consent process and waivers of consent documentation.

**Standard II-4: The IRB or EC provides additional protections for individuals who are vulnerable to coercion or undue influence and who participate in research.**

Element II.4.A. The IRB or EC has and follows written policies and procedures for determining the risks to vulnerable populations and ensuring that additional protections are provided as required by the proposed research and applicable law, codes, regulations, and guidance.

Element II.4.B. The IRB or EC has and follows written policies and procedures requiring appropriate protections for prospective participants who cannot give consent or whose decision-making capacity is in question.

Element II.4.C. The IRB or EC has and follows written policies and procedures for making exceptions to informed consent requirements in protocols for emergency situations and appropriately reviews such protocols.

**Standard II-5: The IRB or EC maintains documentation of its activities.**

Element II.5.A. The IRB or EC maintains a complete set of materials relevant to review of the research for a period of time sufficient to meet legal and regulatory requirements, Sponsor requirements, and organizational policies and procedures.

Element II.5.B. The IRB or EC documents discussions and decisions on research studies and activities in accordance with legal and regulatory requirements, Sponsor requirements, and organizational policies and procedures.

## **Domain III: Researchers and Research Staff**

**Commentary:** The environment in which Researchers and Research Staff conduct research and the type of research they conduct influence their roles and responsibilities. Competent, informed, conscientious, compassionate and responsible Researchers and Research Staff provide the best possible protection for research participants. This Domain of Standards sets forth requirements for Researchers and Research Staff involved in research involving human participants. As part of its Human Research Protection Program, an Organization can improve its protection of research participants if it has arrangements for ascertaining and enhancing the competence of Researchers and Research Staff.

**Standard III-1: In addition to following applicable laws and regulations, Researchers and Research Staff adhere to ethical principles and standards appropriate for their discipline. In designing and conducting research studies, Researchers and Research Staff have the protection of the rights and welfare of research participants as a primary concern.**

Element III.1.A. Researchers and Research Staff know which of the activities they conduct are overseen by the Human Research Protection Program, and they seek guidance when appropriate.

Element III.1.B. Researchers and Research Staff identify and make transparent financial and other interests that might affect relationships with research participants or the outcome of the research and, with the Organization, identify and manage, minimize, or eliminate such interests.

Element III.1.C. Researchers and Research Staff employ sound study design in accordance with the standards of the discipline.

Element III.1.D. Researchers and Research Staff determine that the resources necessary to protect participants are present before conducting each research study.

Element III.1.E. Researchers and Research Staff minimize risk and maximize potential benefits when designing research.

Element III.1.F. Researchers and Research Staff recruit participants in a fair and equitable manner, weighing the potential benefits of the research against their vulnerability and the risks to participants.

Element III.1.G. Researchers and Research Staff employ consent processes and methods of documentation appropriate to the type of research and the study population, emphasizing the importance of participant comprehension and voluntary participation.

Element III.1.H. Researchers and Research Staff have a process to address participants' concerns, complaints, or requests for information.

**Standard III-2: Researchers and Research Staff meet requirements for conducting research with participants and comply with all applicable laws, codes, regulations, and guidance; the Organization's policies and procedures for protecting research participants; and the IRB's or EC's determinations.**

Element III.2.A. Researchers and Research Staff are qualified by training and experience for their research roles, including knowledge of applicable federal, state, and local regulations; relevant professional standards; and the Organization's policies and procedures regarding the protection of research participants.

Element III.2.B. Researchers and Research Staff follow the requirements of the research plan or protocol, adhere to the Organization's policies and procedures, and the determinations of the IRB or EC.

Element III.2.C. Researchers and Research Staff report unanticipated problems involving risks to participants or others, non-compliance, suspensions or terminations of research, complaints, data and safety monitoring reports during a research study in accordance with applicable laws, codes, regulations and guidance, the Organization's policies and procedures, or the IRB's or EC's requirements.

Element III.2.D. Researchers maintain appropriate oversight of each research study, as well as Research Staff and trainees, and appropriately delegate research responsibilities.